Aerosol Delivery in a Comprehensive Asthma Management Program for Children

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NMC San Diego Pediatric Department

- 250, 000 children eligible for care in Tricare Region 9 (S. California)
- Estimate of 15,000 pediatric asthma patients
- 100,000 outpatient visits / yr
- 1,500 pediatric medical admissions / yr
- Large pediatric training center
  - 25 Pediatric Residents
  - 15 General Pediatricians, 22 Subspecialist
  - 8 PNPs, 3 clinic based RT
  - Asthma Clinical Nurse Coordinator

Background

- 1995- comprehensive pediatric asthma inpatient clinical pathway
- 1997- asthma pathway revised to coincide with NHLBI EPR 2
- 1998- outpatient pediatric asthma clinical pathway
- 1998- converted to aerosol delivery via pMDI + VHC

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- Sept 98’ the Pediatric Dept.
  - Discontinued ordering SVN equipment for home use
  - Clinic aerosol treatments given via pMDI+AC
  - Hospitalized asthma patients receive pMDI+AC
- April 04’
  - TRIACRE West standardization of VHC, PFM, and SVN

Strategies

1. Understand the importance of aerosol therapy in asthma management
2. Understand the literature on delivery options
3. Choose the appropriate valved holding chamber
4. Train and monitor the teachers
5. Convince and convert patients and caregivers

Strategies

6. Recognize and address obstacles to conversion
7. Monitor clinical safety and efficacy
8. Trust……but verify!
9. Periodically evaluate customer satisfaction
10. Measure outcomes and cost savings

Background

- Asthma is a chronic inflammatory airways disease affecting 5 million children in the United States.
- In 2002 over 12 million school days were lost by children with asthma (20-30 % of all school absences)
- Lost productivity of their parents equaled nearly $1 billion (U.S.)
- Annual asthma costs are > $8 billion

Uncontrolled Asthma is Expensive

- Each year in children under 17 yo
  - 3 million doctor visits
  - 570,000 ED trips
  - 164,000 hospitalizations
  - > 500 deaths

Background

- Inhaled medications are essential for the management of chronic airways disease
  - Delivery of relatively small doses
  - Directly to intended site of action
  - High local concentration
  - Minimize systemic side effects
  - High therapeutic ratio

Background

- Benefits of inhaled therapy
  - Rapid onset of action
  - Increased safety
  - Reduced drug usage
  - Cost-effective

pMDI...The Gold Standard

- Portable
- Tamper-proof
- Remaining produc uncontaminated
- Accurate dosing m
- Multiple doses
- Inexpensive
- Mature technology
- High respirable fraction
- Easy to use

pMDI Add-On Devices

- **Spacer = is a device to hold pMDI medication, prior to inhalation. It does not have any valves!**

  Examples: InspirEase, Plastic soda bottle, Toilet paper roll, etc.

- **VHC = a device to hold pMDI medication, It has valves an inspiratory valve and may also have an expiratory valve.**

  Examples: AeroChamber, NebuChamber, Vortex, Optichamber

Valved Holding Chamber

- Slows down droplets
- Trap large droplets
- Exhalation diversion
- Oropharyngeal deposition
- Ameliorate the bad taste of drug
- Eliminate the “cold freon” effect
- Reduce drug loss associated with poor hand-breath coordination

Clinical Efficacy Studies of SVN vs. pMDI+VHC

Acute Asthma

- William JR. 96’
  - 60 children 6-18 years in ED with acute asthma
  - PARI-JET II vs. Aerochamber vs. ACE
  - Outcome measures changes in PEFR and RR
  - No difference between delivery methods
  - pMDI + VHC more cost effective
- Schuh S. 99’
  - 90 children 5-17 years in ED, outcome FEV_1
  - pMDI +Aerochamber (high & low dose) vs. SVN
  - No difference between groups, ^HR with SVN

Randomized Trial of Salbutamol via MDI +Spacer vs. SVN for Acute Wheezing in Children < 2 Years old

- ED based, 123 patients presenting with moderate-severe wheezing
- Most < 12 months age
- NEB - .25mg/kg salbutamol Q13 min x 3
- MDI+VHC- 2 puffs salbutamol Q10 min x 5
- Successful clinical response
  - After 60 mins: 91% MDI , 71 % NEB
  - After 120 mins: 100% MDI, 94% NEB

Rubilar L, et al. Pediatr Pulmonol 200;29:264-269.

High-Dose Albuterol by MDI+Spacer vs. SVN in Preschool Wheezers

- Randomized, DP, parallel group equivalence study
- 64 children, 12-60 months of age with acute recurrent wheezing
- Pediatric ED ward in 2 tertiary care hospitals
- Babyhaler spacer- 50 ug/kg, SVN- 150 ug/kg
- 3 treatments at 20 minute intervals
- Equivalent clinical response
- 94% parents preferred MDI+VHC

Ploin D, et al. Pediatrics 2000;106:311-317

Cost and Effectiveness of Spacer vs. Nebulizer in Young Children with Moderate and Severe Acute Asthma

- Randomized DB, PC trial in ED, subjects 1-4 yo
  - 6 p albuterol via MDI+ Aerochamber
  - 2.5 mg by nebulizer
  - Repeated Q 20 min until well or total of 6
  - Monitored- clinical score, HR, RR, O_2 sat, chest exam
- pMDI+VHC vs. Neb
  - Equal- clinical score, RR, O_2 sat
  - Greater reduction in wheezing
  - ^ HR with neb
  - 86% children and 85% parents preferred spacer

Leversha AM, et al. J Pediatr 2000.136:497-502.

Lower Airway Deposition Studies

- Tal 96’
  - Radio-labeled salbutamol via masked Aerochamber in children with airways disease age 3mo-5 years
  - Widespread drug deposition in central and peripheral airways
  - Mean deposition 1.97%, crying infant-.35%
- Wildhaber JH 99’
  - Compared SVN to pMDI + VHC
  - Children 2-9 years old
  - Equal percentages of nominal dose in lower airway

Small Volume Nebulizer

- Less dependent on patient cooperation
- Expensive
- Time consuming
- Bulky and unwieldy + paraphernalia
- Dependent on power source
- Risk of infection spread
- Intra-device and inter-device variability
- Increased risk of side effects

MDI +Valved Holding Chamber

- Equal or better efficacy and less side effects
- Improved patient adherence to therapy
- Immediate use with little preparation
- Can be used in many settings
- Treatment effect can be titrated
- Effective in ED for very young wheezers
- Significant cost benefit

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Choosing an Add-On Device for Children

- **Approximately a dozen spacer devices**
  - **Open Tube (Azmacort)**
  - **Holding Chambers (Aerochamber, Nebuhaler)**
  - **Reverse-flow (Optihaler, Inspirease)**

- **Numerous *in vitro* and *in vivo* published studies describing use and effect on delivery of pMDI aerosols**

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Choosing an Add-On Device for Children

- **Performance in children is affected by:**
  - **Volume (no clinical benefit to > 150 cc)**
  - **Presence of valve (eliminates coordination)**
  - **Attached masks + one way valve**
  - **Shape (diameter & length)**
  - **Manufacturing material (electrostatic charge)**
- **Aerochamber and Aerochamber with Mask were chosen as VHC of choice**

Why AeroChamber?

- Size user friendly, encourages patient compliance, 145 ml ideal volume
- Low resistance tamper resistant one-way valves
- Exhalation valve with masks

Why AeroChamber?

- Low dead space with masks
  - Permits comfortable and effortless tidal breathing
  - Avoids re-breathing of exhaled air
- Proven by almost 20 years of laboratory and positive clinical research and response
- Peer reviewed studies on improved patient outcomes, better lower airway lung deposition

Aerosol Prescriptions

- Prescribed to 16% of US population
- Estimated that $1 billion of wasted medication
  - Poor aerosol device selection
  - Inadequate patient training
  - Mismatch of device to patient

Medical Personnel's Knowledge & Ability to use MDI's & VHC's

GROUPS

- **Nurses**
- **Physicians**
- **Pharmacists**
- **Respiratory Therapists**

Medical Personnel's Knowledge of and Ability to Use Aerochamber

Steps	MD Mistakes
1-Remove caps and connect	20%
2-Hold inhaler & VHC and shake	30%
3-Exhale to FRC or RV	50%
4-Tilt head back or keep level	40%
5-Insert mouthpiece between lips	20%
6-Actuate canister once	40%

Hanania NA, et al. Chest 1994;105:111-116.

Medical Personnel's Knowledge of and Ability to Use Aerochamber

Steps #	MD Mistakes
7-Inhale slowly and deeply	40%
8-Should not hear a whistling sound	70%
9-Hold breath for 5-10 secs	60%
(may repeat # 7-9)	
10-Wait 20-30 seconds	50%
11-Shake before a second actuation	50%

Hanania NA, et al. Chest 1994;105:111-116.

Medical Personnel's Knowledge of and Ability to Use Aerochamber

- Conclusions
  - Medical personnel lack rudimentary skills
  - Nurses and MD's seldom receive formal training
  - Likely results in the poor patient technique
  - Respiratory therapists most likely to use properly
  - Masked Aerochamber likely less well understood

Poor Inhalation Technique Even After Instruction in Children with Asthma

- 66 newly referred children with asthma
  - 60 / 66 had received instruction from PCP
  - 58% performed all steps correctly
  - 97% thought they had proper technique
- 29 control patients followed in asthma clinic
  - 93% performed all steps correctly
- Major difference was extent of training
  - PCP relied on verbal instruction for 5 mins
  - Asthma clinic used demonstration til correct (30 mins)

Kamps AWA, et al. Pediatr Pulmonol 2000;29:39-42.

Common Mistakes!!

- Not shaking the canister
- Failure to forcefully exhale before breathing in
- Pressing inhaler repeatedly while breathing in
- Not waiting 30-60 seconds between puffs
- Not holding breath after deep inspiration (8-10 seconds)
- Breathing in through the nose, using mouthpiece

- Stop breathing in after actuation
- Uneven and / or too shallow inspiration
- Not shaking the canister before the 2nd , 3rd , every puff.
- Breathing in too fast, Not aware of what the “whistle” means
- Breathing in first, activating MDI second

pMDI +Valved Holding Chamber

- Most studies report equal or better efficacy and less side effects
- Improved patient adherence to therapy
- Immediate use with little preparation
- Can be used in many settings
- Treatment effect can be titrated
- Significant cost benefit

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Converting Patients and Parents

- **Instructed for years that “bad” asthma attacks = SVN and pMDI+VHC = mild flares and maintenance**
- **Use of pMDI +VHC delivery of rescue medications in ED/Clinic/Ward**
- **Discuss in lay terms the aerosol literature**
- **Be confident in your approach**

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Converting Patients and Parents

- **Emphasize**
  - **Convenience**
  - **Time savings**
  - **Portability**
- **“Try it, you’ll like it”**
- **Parents / patients embrace conversion once they recognize the benefits**

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Required Resources

- Support from
  - Pediatric Department Head
  - Respiratory Therapy Department Head
  - Respiratory specialist (Allergist, Pulmonologist)
- Availability of valved holding chambers
- Initial start up expense
- Printed patient instructions to accompany demonstration
- Availability for patient problems

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mplementing a Paradigm Shift

- Comprehensive educational program
- “Physician Champion”
- Assemble Training team
- Identify target audience and the gap
- Visit all areas where pediatric aerosols given
- Conduct short, frequent “hands on” sessions and be available for “problem” patients
- Frequent refreshers

Ongoing Monitoring

- Assessing clinical efficacy
  - Clinical Pathway Outcome Tool
    - Hospital admissions
    - ED / Urgent care visits
    - Number of oral steroid courses
    - Missed school days
- Assessing for side effects
  - Stadiometer heights
  - Oropharyngeal exam for thrush
- Adherence
  - Annual drug utilization review

Ongoing Monitoring

- Reassessing patient / parent skills
  - Bring medications + VHC to each visit
  - Demonstrate technique in clinic
- Patient / Parent / Provider Satisfaction
  - Semi- annual formal written questionnaire
- Counting dollars
  - Quarterly report from Managed Care Office
    - # of SVN dispensed
  - Monthly # of Aerochambers from RT
- Reassessing Trainer skills
  - Suprise quiz

Demonstrated use of Asthma Gadgets by Children with Acute Asthma

- Children aged 2-18 presenting to urban ED with acute asthma exacerbation
- 208 subjects
  - 73 (35%) used MDI without VHC
  - 135 (65%) used MDI+VHC, 61 used a facemask
- MDI alone-25% perfect technique, 50% multiple errors
- MDI+VHC- 44% multiple errors

Scarfone RJ, et al. Arch Pediatr Adolesc Med 2002; 156:378-383.

Factors Affecting Total Respirable Dose Delivered by MDI

- Not shaking the MDI before use reduced the total (26%) and respirable (36%)
- 2 actuations separated by 1 second had no effect on total, but reduced respirable dose (16%)
- Storing MDI stem down reduced total (25%) and respirable (23%) dose delivered in 1st actuation

Everard ML, et al. Thorax 1995; 50:746-749.

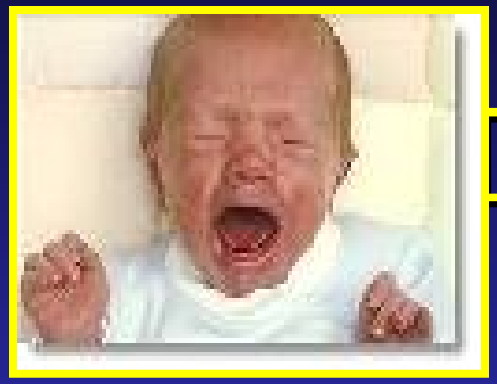
Aerosol Therapy with VHC Importance of Facemask Seal

- Evaluated ability of parents to provide a good mask-face seal in infants and toddlers
- Compared 3 commonly used VHC with a Hans Rudolph pediatric anesthesia mask
- Reduced ventilation resulting from facemask leak reduces dose delivered to mouth
- Aerochamber provided best seal
- Intra-individual variability (24-48%)

Amirav I, Newhouse MT. Pediatrics 2001;108:389-394.

Aerosol Therapy with VHC Importance of Facemask Seal

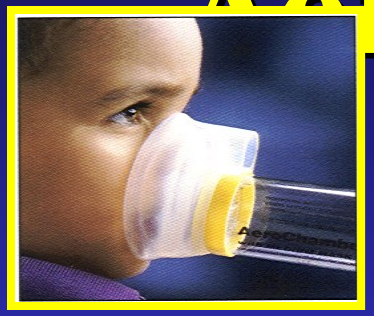
- Nebuchamber variability 2 fold greater
- Coached sessions superior to uncoached
- Conclusions
  - Always assume that delivery is inefficient or sub optimal when asthma control is difficult
  - Always have the parent demonstrate
  - Re-evaluate over time skills may diminish



The Crying Child

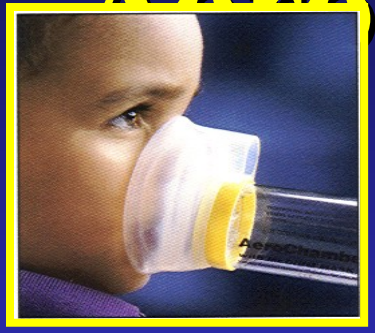
- Iles, et al. 99’- crying significantly reduces absorption of aerosolized drug in infants
  - 15 infants (13 months), 8- with CLD,7- controls
  - 20 mg nebulized sodium cromoglicate
  - Settled infants excreted .43% neb dose
  - Distressed infants excreted .11% neb dose
- Wildhaber, et al. 99’- lung deposition and therapeutic index much lower in a screaming younger child
  - In vivo deposition of radio-labeled salbutamol in 17 children age 2-9 yrs SVN vs. MDI+Aerochamber

Strategies for Masked Aerochamber Treatments in the Toddler



- Let the child play with the Aerochamber
- DO NOT force the mask on the child
- Make the experience fun
- Treatment while they are doing fun things
- Stickers on the Aerochamber

Strategies for Masked Aerochamber Treatments in the Toddler



- Practice short “pretend” treatments
- Give high praise and rewards
- Treatments to teddy bears, dolls, parent
- Last resort administer while asleep

Monitoring Satisfaction
Healthcare Provider Questionnaire

- What problems have you encountered?
- Do you believe the delivery methods are comparable? If not, which is better?
- Have you experienced any time savings and if so are you more efficient in other areas?
- What, if any, has this conversion had on your job satisfaction?
- What is your impression of our patient & family's satisfaction with the conversion?

Substituting MDI+VHC for SVN

- 700 bed tertiary care university hospital
- Converted > 60% treatments to MDI
- RT Time reduced from 1,576 hr / mo to 992 hr/mo
- Total cost reduction of $83,000 / yr
- Patient charges lowered $300,00 / yr
- Improved RT staff satisfaction due to better use of time

Bowton DL, et al. Chest 1992;101:305-308

Substituting MDI+VHC for SVN

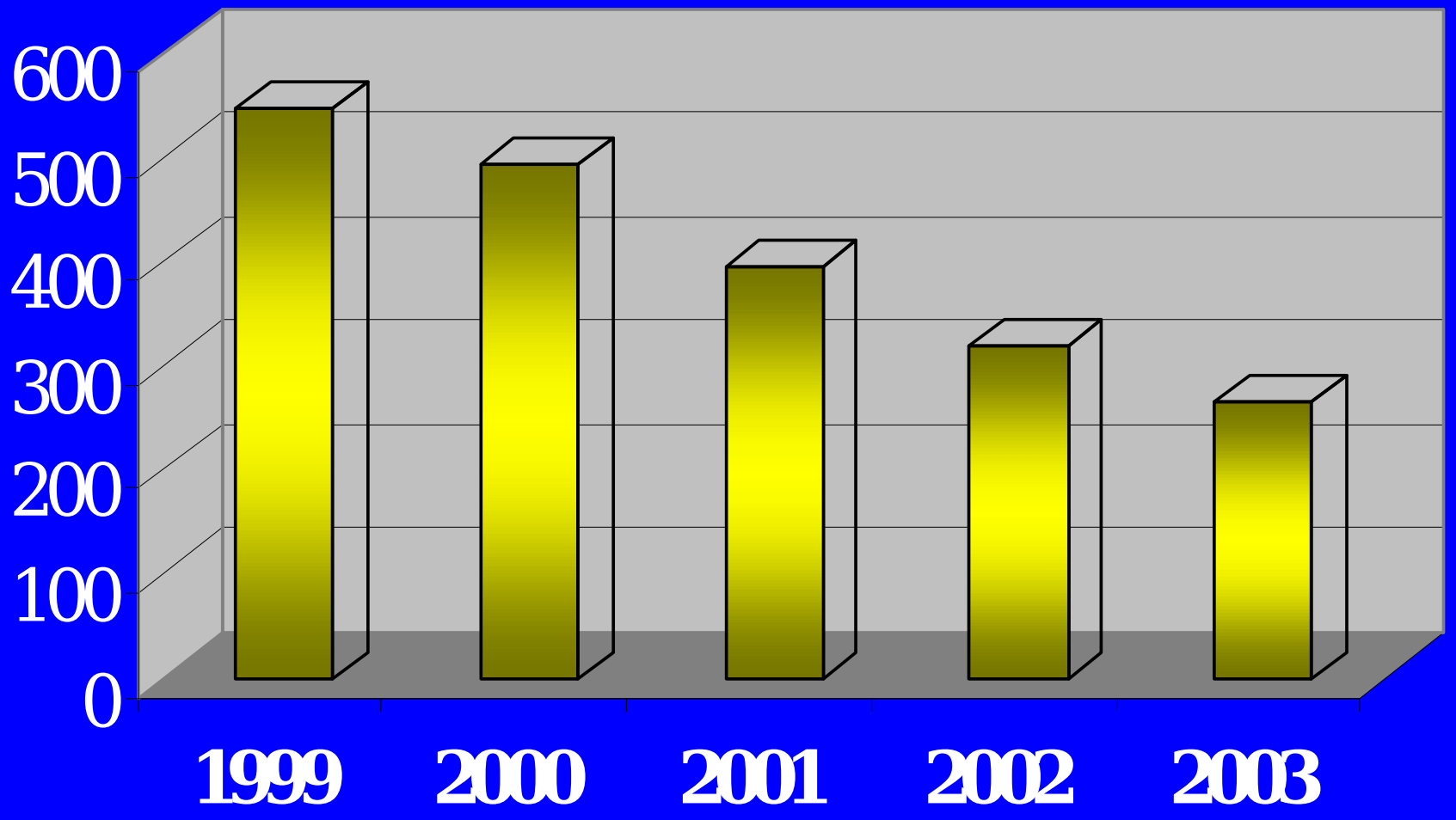
- Success based on several practical factors
  - Comprehensive educational programs for RT / MD
  - Assure that RT understands rationale
  - Allow RT to determine which method works best for each patient
- Actual dollar savings realized will vary

Cost Comparison of Inpatient Aerosol Albuterol Treatment

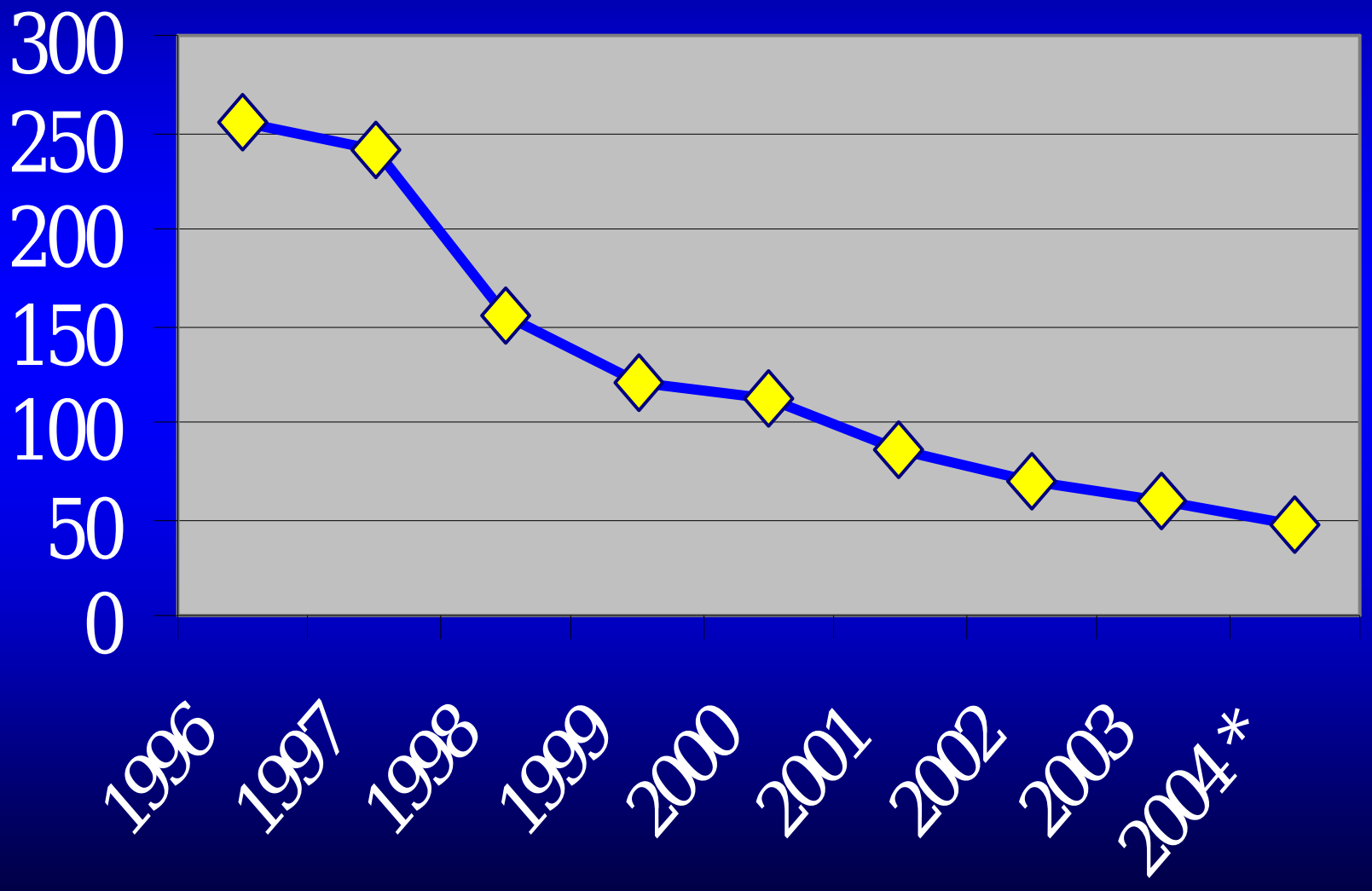
	SVN	pMDI+Aerochamber®
Equipment	$.90	$.015
Albuterol	$.10 (.5cc)	$.04 (4 puffs)
Normal Saline	$.07	N/A
* RT Time	$6.00 (20 min)	$3.00 (10 min)
Total Cost	$7.07	$3.06

* **Based on $18.00 / hour RT pay scale**

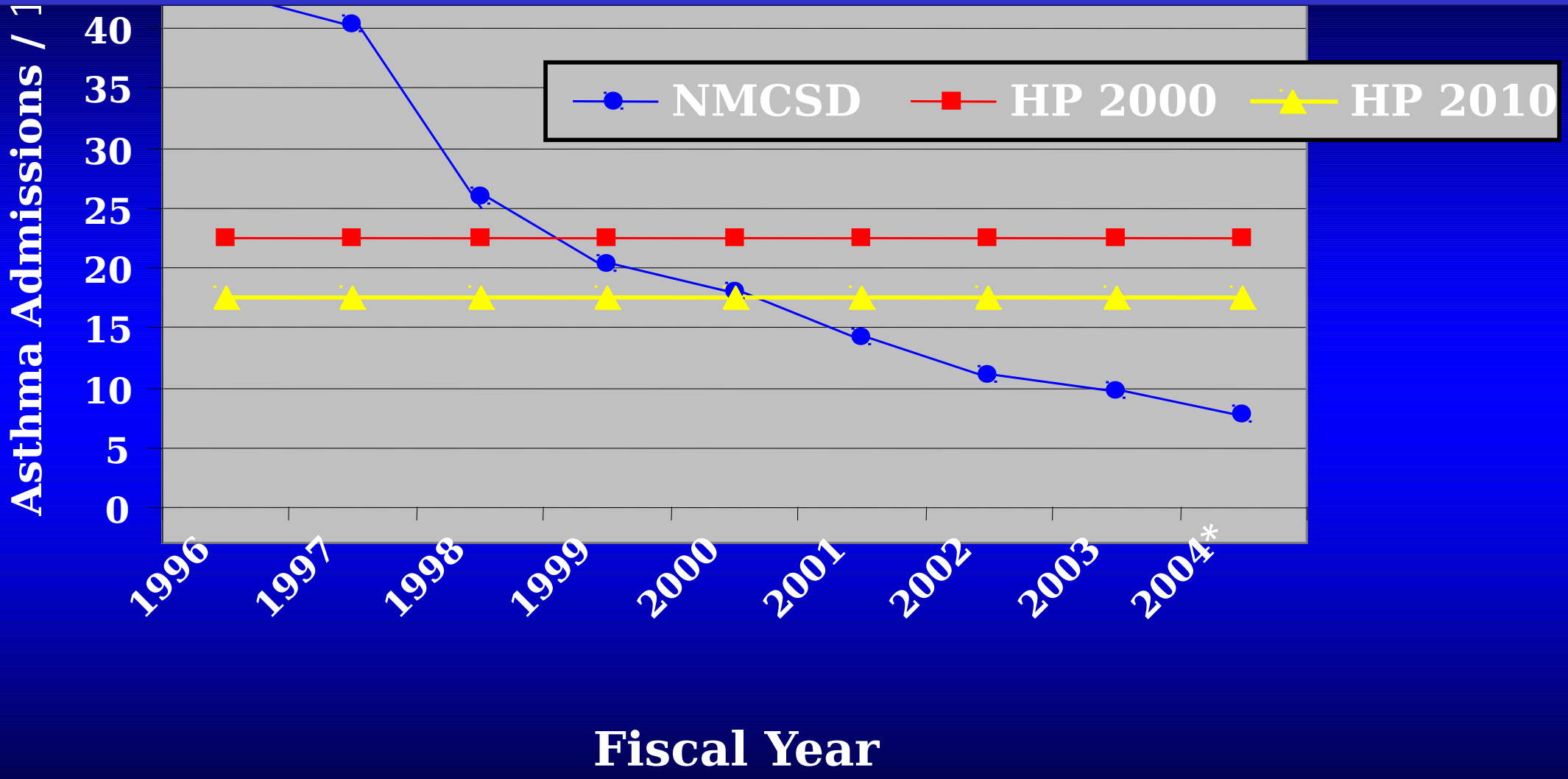
MCSD Emergency Department Pediatric Asthma Visits



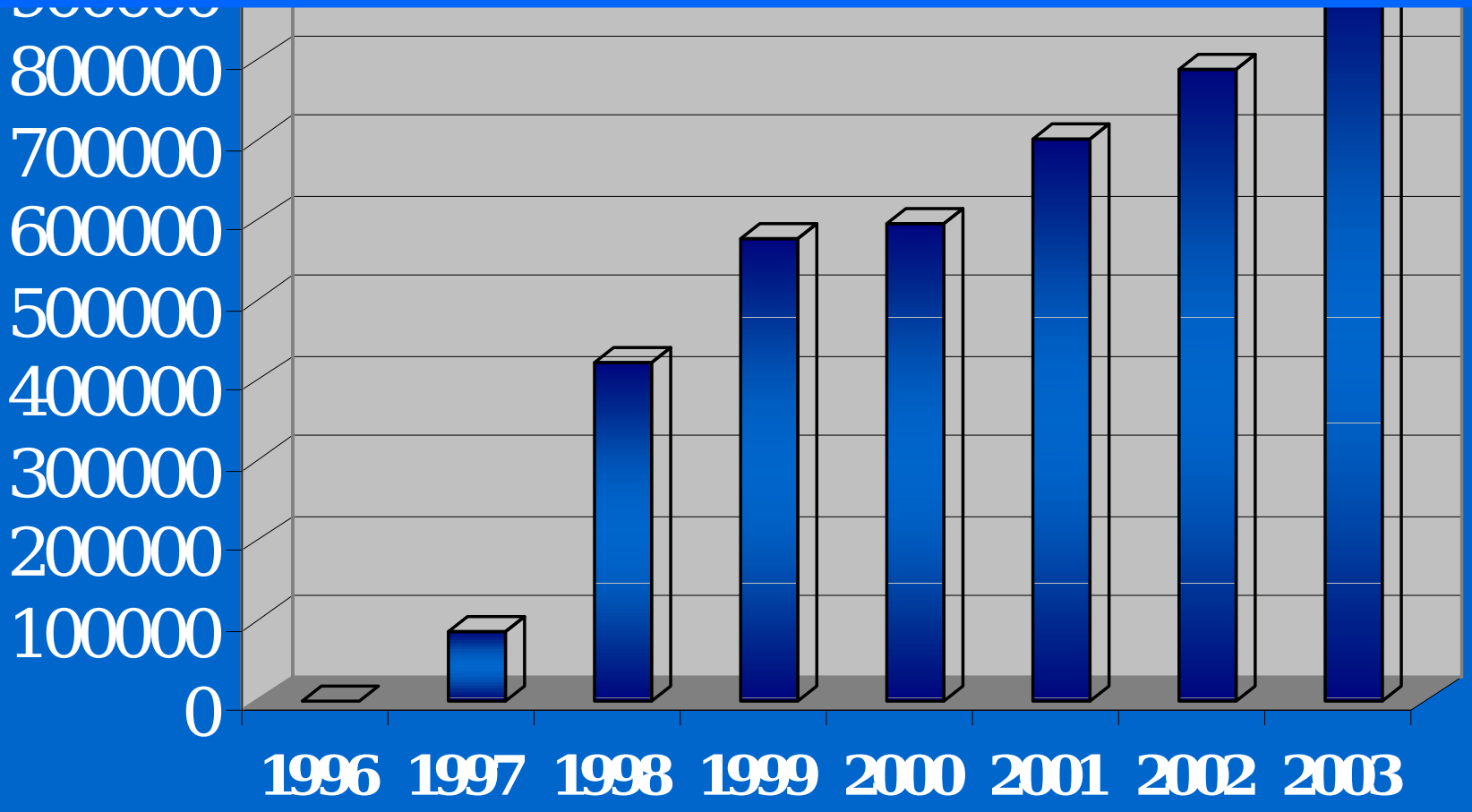
Yearly Pediatric Asthma Admissions



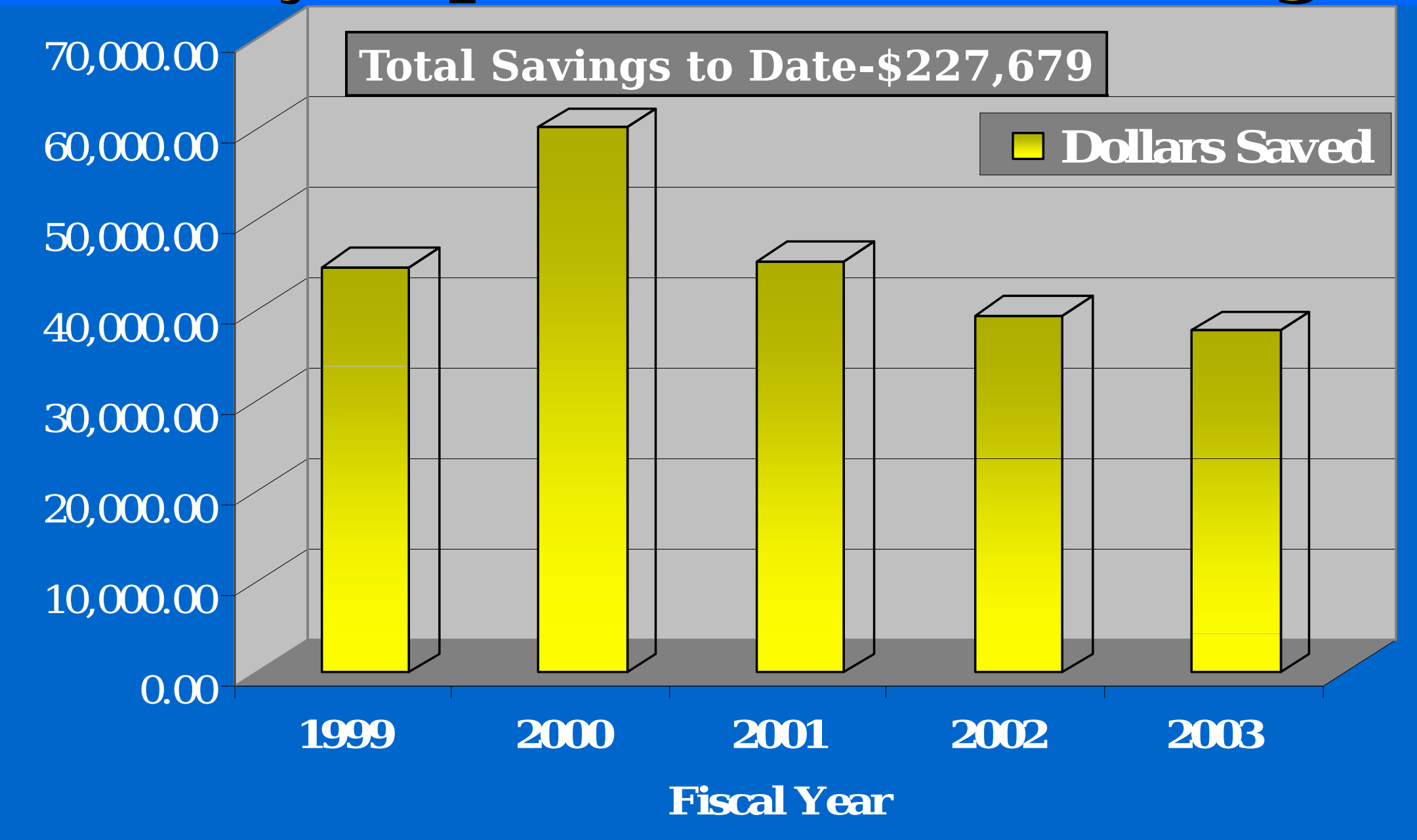
Naval Medical Center San Diego Pediatric Asthma Hospitalization Rate vs. Healthy People 2000 and 2010 Benchmarks



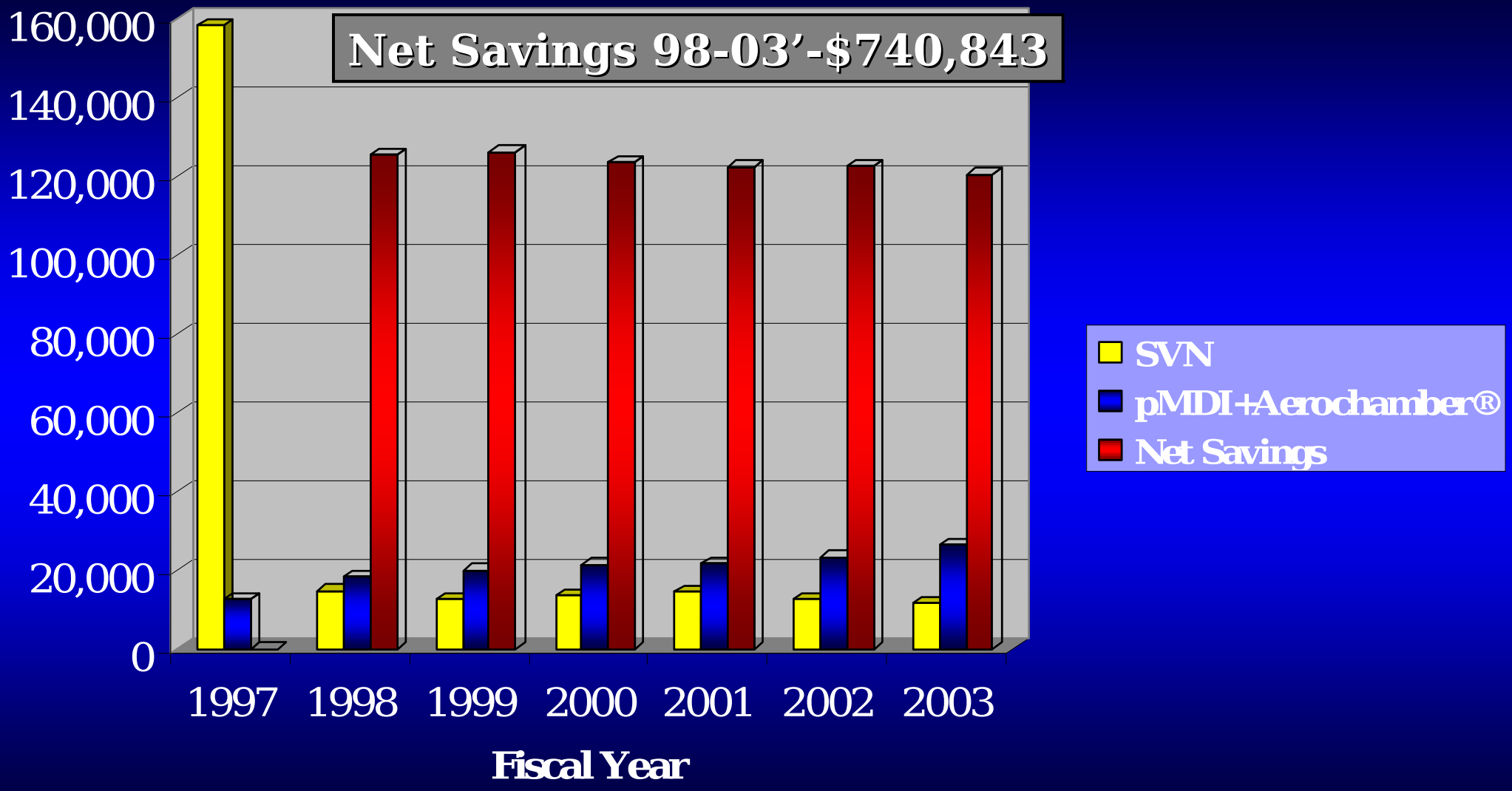
Naval Medical Center San Diego Pediatric Asthma Inpatient Cost Savings Compared to Fiscal Year 1996



Yearly Inpatient Cost Savings



Average Yearly Cost of SVN vs. pMDI +Aerochamber® for Delivery of Aerosols in Children with Asthma



Future Directions

- Need to incorporate current aerosol delivery research into professional school's curriculum
- Develop more efficient ways to teach patients / parents / providers
- More pediatric studies on
  - Cost savings
  - Enhanced adherence with pMDI+VHC
  - Dosing compared to SVN
  - Dosing with HFA pMDI

Take Home Points

- Aerosol therapy is an essential component of any comprehensive asthma management program
- Aerosol asthma medications can be safely and effectively delivered to children at any age via pMDI +VHC
- Conversion from SVN to pMDI+VHC can be accomplished using a systematic evidence-based approach
- Conversion can result in increased patient satisfaction, cost savings, and improved clinical outcomes